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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,278	07/31/2001	Herm Snyder	0068.00	4703

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NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

YEBASSA, DESTA LETTA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,278

Applicant(s)

SNYDER ET AL.

Examiner

Desta L. Yebassa

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 19-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt is acknowledged of the remarks and amendment response received by office on 11/30/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 - ~~24~~, and 26 – 32 are rejected under 35 U.S.C. 102 (b) as being anticipated by US patent 4,671,489 to Ketcham.

Applicant argued that Ketcham does not disclose a vibratable element and a separate plate comprising holes. Ketcham teaches about vibrating members and a separate plate comprising holes on (column 2, lines 65, column 3, lines 5-20, and column 3, lines 55-65). Therefore, the rejection is persuasive as stated previously in the non-final rejection as follows.

Ketcham teaches an apparatus and process for producing liquid droplets having a narrow size distribution, wherein this liquid streams are forced under pressure through a plurality of orifices in an orifice plate, wherein the thin liquid streams are vibrated to cause the breakup of each stream into droplets having a narrow size distribution (abstract). Ketcham further teaches that the mean orifice diameter is between from

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about 1 micron to about 10 microns, or between from about 2 microns to about 5 microns, and that the diameter of the largest orifice in the plate is not greater than about three times the diameter of the smallest orifice in the plate. The range of 2 to 5 microns clearly reads on Applicant's limitation that the particle size distribution is less than 4 microns. Additionally, the discussion of small and large orifice size anticipates Applicant's limitations found in claims 26-28.

Ketcham also teaches a processing step, after the formation of the droplets, wherein the droplets are processed into particles having a narrow size distribution and a mean number diameter of up to about 5 microns (claim 24). This processing step may comprise entraining said droplets in an inert dilution gas, which provides a drying medium for removal of the liquid carrier medium by evaporation. Ketcham also teaches that the processing step may include steps such as cooling, freezing, heating, chemical reaction, and the like (c 8, 162 - c 9, 112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 22 and 23 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ketcham. As discussed above, Ketcham teaches a size of between 1 to 10 microns, or between 2 and 5 microns. This certainly reads on Applicant's limitation that the particle size distribution be within a 4-micron range. Furthermore, Applicant claims a range of 3 microns, or 1.5 microns. However, Ketcham teaches that the largest diameter is not greater than about three times the smallest diameter. If the largest diameter is 5 microns, then the smallest diameter could be no less than 1.7. This means a difference of 3.3. Although this is larger than the range of 3 microns, or the range of 1.5 microns claimed by Applicant in claims 22 and 23, it is the position of the examiner that the teachings of Ketcham clearly suggest Applicant's claimed ranges. Ketcham is using the same method to achieve the same end result. Furthermore, the above range of 3.3 is the largest the range could possibly be if the orifices were between 2 and 5 microns in size. However, Ketcham teaches that this is the high end of the range. One skilled in the art would interpret the teachings of Ketcham to include particle size distributions as small as 1.5, based on the purpose and the technique employed by Ketcham.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ketcham in view of JP 408015955 to Noda et al. Ketcham teach that their apparatus contains a vibrating means, but they do not specify what that vibrating means is. Noda et al. are relied upon for the teaching that coupling a piezoelectric element to a vibratable surface

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can result in the vibration of that surface. Therefore, Noda et al. are relied upon to teach piezoelectric elements are vibrating means. It is the position of the examiner that one of ordinary skill in the art would have been motivated to use any type of vibrating means, including a piezoelectric element, as taught by Noda et al. as the vibrating means discussed by Ketcham. Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill in the art at time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta Yebassa whose telephone number is 571-272-8511. The examiner can be normally be reached on Monday- Friday 8 Am to 6 Pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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